K130468

Summary of Safety and Effectiveness

MAR 19 2013

"510(K) SUMMARY"

Submitted By/
Contact Person:

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Date Prepared: February 19, 2013

1.1. Trade/Proprietary Name: Orbit Infusion Set

1.2. Common/Usual Name: Subcutaneous Infusion Set

1.3. Classification Name: Set, Administration, Intravascular

1.4. Classification:

Class:	II
Panel:	80
Product Code:	FPA
Cite:	21 CFR 880.5440

1.5. Purpose of Submission: Ypsomed acquired the Orbit infusion set business of ICU Medical Inc., USA in November 2011, including 510(k) K033290 under which the devices were cleared for marketing as the Talon Infusion Set.
The purpose of this submission is to update the premarket notification file to reflect the product as manufactured. The only additional change is to modify the labeling to reflect Ypsomed, which previously had been a distributor of the product manufactured by ICU Medical.

1.6. Substantial Equivalence: The Orbit Infusion Sets are substantially equivalent to the Talon Infusion Set (K033290). The equivalence is supported by the attached documentation.

1.7. Device Description The Orbit Infusion Set is used for the subcutaneous delivery of fluids and medication from an external infusion pump.

Orbit Infusion sets are comprised of tubing that is connected on one end to the medication reservoir of the infusion pump using a luer lock connection and on the other end to the patient, attached to the skin by an adhesive base, anchoring a catheter that is inserted into the subcutaneous tissue. These sets have a patented design feature which allows the tubing to freely rotate 360° at the adhesive attachment and to disconnect the tubing set from the infusion base.

1.8. Intended Use: The intended use of the modified device remains the same as the predicate device (Talon Infusion Set, K033290): Orbit Infusion Sets are intended for the subcutaneous delivery of fluids and medication, such as insulin, from an external infusion pump.

1.9. Technological Characteristics: Orbit Infusion Sets are considered substantial equivalent to K033290, Talon Infusion Set, in intended use and in the device's operating principles.

1.10. Performance and Safety Data: Ypsomed has performed the relevant assessments specified in the following international and internal standards and protocols and confirmed compliance of the modified devices and equivalence to the predicate devices.
The Orbit Infusion Sets have met the requirements of the relevant sections of the following standards:

Test	**Specification**
Material strength of steel cannula	Material strength per ISO 9626
Activated pressure leak	No leak when subjected to pumping pressures up to 20psi under normal delivery conditions and occluded fluid path conditions
Penetration force	Needle and catheter shall penetrate a 0.025 inch thick membrane with a speed of 50mm/min. and a force of less than 0.8N
Needle retention	No separation of the needle from the cap when subjected to a minimum force of 10N (ISO 10555-1, Annex B)
Catheter retention	No separation of the catheter from the base when subjected to a minimum force of 3N (ISO 8536-8)
Bond strength of tubing/fittings	No separation of the tubing assembly when subjected to a static tensile force of 15N for 15 sec.
Bond strength of tape/base	No separation of the tape from the base when subjected to a minimum force of 18N
Engagement force tubing cap/base	The cap locks on the base with a force less than 13N
Disengagement force tubing cap/base	The force to remove the tubing cap from the base is more than 13N

Occlusion test	No occlusion of the device when tested with a water flow at a hydrostatic pressure of 0.1 bar
Tape adhesion	Removal of adhesive from a stainless steel plate with a 90 degree peel force of minimum 2.5N (0.56lbs)

The verifications have shown evidence that the Orbit Infusion Sets meet the acceptance criteria of these standards. Based on the results it can be concluded that the device performance and safety are acceptable for the product.

1.11. Conclusion

Ypsomed AG concludes based on the information presented that the modified product is substantially equivalent to the current product legally approved in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Dr. Benjamin Reinmann
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March 19, 2013

Re: K130468
Trade/Device Name: Orbit Infusion Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 22, 2013
Received: February 25, 2013

Dear Dr. Reinmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 130468

Device Name: Orbit Infusion Sets

Indications For Use: Orbit Infusion Sets are intended for the subcutaneous delivery of fluids and medication, such as insulin, from an external infusion pump.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130468